

REMARKS

Claim 1 has been amended to recite a non-reactive pressure sensitive adhesive composition comprising an acrylic polymer and a therapeutic agent. Claim 1 has been further amended to limit the polymerizable non-cyclic nitrogen-containing monomers as t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles or mixtures thereof. Support for the foregoing amendment is replete throughout the application, and may be found for instance in page 5, lines 3-5 and page 7, lines 1-5.

Similarly, Claims 12 and 22 have been amended to recite a transdermal drug delivery system comprising a non-reactive pressure sensitive adhesive composition, and has further limited the polymerizable non-cyclic nitrogen-containing monomers as t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles or mixtures thereof. Support for the foregoing amendment is replete throughout the application, and may be found for instance in page 5, lines 3-5 and page 7, lines 1-5.

No new matter has been added. Entry is requested. Accordingly, upon entry hereof, claims 1, 3-7, 9-19 and 21-23 will be under consideration or reconsideration.

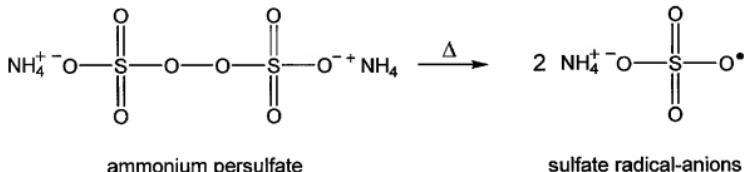
Applicants turn to the substance of the Action, in which rejections have been advanced against the pending claims under 35 U.S.C. §§ 102 and 103.

Rejection under 35 U.S.C. § 102

Claims 1, 3-7 and 9 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Weaver et al. (U.S. Patent 3,491,070, hereinafter “Weaver”). The Examiner further maintains

the position that ammonium persulfate is a therapeutic agent, referring to US 5,827,505 to support this position.

As an initial matter, Applicants wish to correct Examiner's mischaracterization of ammonium persulfate because this would not have an antimicrobial effect in the instant composition (Office Action, page 5, third paragraph). A skilled artisan understands that the thermal decomposition of ammonium persulfate has the following reaction mechanism:



The decomposed ammonium sulfate radical anion no longer can oxidize and thus, it is no longer a bleaching agent and does not have any therapeutic effect. Moreover, the anion initiates a chain reaction and is completely consumed in the polymerization to become a part of the polymer. The resultant polymer has a molecular weight that is far greater than what is permeable into the skin. As such, Weaver does not comprise a therapeutic agent, and fails to disclose each and every element of the claimed invention, and it is respectfully submitted that the claims are allowable over Weaver.

Although Applicants do not agree, solely in order to expedite prosecution of the present application, claim 1 has been amended to recite that the adhesive composition is a non-reactive pressure sensitive adhesive composition. Claim 1 has been further amended to recite that the polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl

acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, and mixtures thereof. Claims 3-7 and 9 depend from the amended claim 1.

In order for a reference to anticipate, the reference must disclose all the elements of the claim within the four corners of the document, and must also disclose those elements arranged as in the claim. Weaver does not disclose all of the Applicants' claimed elements within the four corners of the document and in the combination claimed by Applicants and, as such, fails to anticipate the claimed invention. Weaver discloses adhesive compositions that comprise a polymer composition based on a specific acrylate monomer (2-ethylhexyl acrylate) and two specific acrylamide monomers (N-octyl acrylamide and methacrylamide). The adhesive of Weaver contains a polymer based on 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide and teaches that all three monomers must be present in the adhesive composition (Weaver, col. 1, lines 65-68). As amended, the instant claim limits the polymerizable non-cyclic nitrogen-containing monomers as only t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, or mixtures. No other monomers are included. Methacrylamide is not included as a possible monomer component of Applicants' acrylic polymer.

Reconsideration and withdrawal of the Section 102 rejections of claims 1, 3-7 and 9 are therefore respectfully requested.

Claims 1, 3-6, 9-14 and 22 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 0 531 938 (hereinafter "EP'938").

As a preliminary matter, Applicants wish to correct Examiner's reference to the teaching of EP'938 as not disclosing any crosslinking after polymerization or any functional groups (Office

Action dated March 31, 2010, page 7, second paragraph). EP'938 indeed discloses post crosslinking the adhesive. EP'938 discloses preparing the acrylic gel material by crosslinking the pressure sensitive adhesive by a suitable crosslinking to prevent oozing (see EP'938, page 5, lines 7-20), and an in situ crosslinking polymerization process (Page 5, lines 18-20). As such, EP'938 discloses at least two different methods of crosslinking after polymerization. Moreover, EP'938 discloses obtaining acrylic ester-based polymers by an alkyl (meth)acrylate and at least one carboxyl group-containing monomer and hydroxyl group-containing monomer, as essential components to control of the amount of crosslinking sites or to control tackiness properties (EP'938, page 4, lines 33-37). Unlike EP'938, the instant invention is directed to a non-reactive pressure sensitive adhesive, which specifically lacks carboxyl groups and hydroxyl group containing monomers. In addition, EP'938 fails to disclose an adhesive that also comprises a therapeutic agent as required in the practice of Applicants' invention. Thus, EP'938 fails to disclose each and every element of the claimed invention, it is respectfully submitted that the claims are allowable over EP'938.

Although Applicants do not agree, solely in order to expedite prosecution of the present application, claims 1, 12 and 22 have been amended to recite that the adhesive composition is a non-reactive pressure sensitive adhesive composition. Claims 1, 12 and 22 have been further amended to recite that the polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, and mixtures thereof. Claims 3-6 and 9-11 depend from the amended claim 1. Claims 13-14 depend from claim 12. As defined in the Specification, page 5, lines 2-5, "non-reactive" denotes

adhesive composition that lack functional groups containing reactive hydrogen moieties such as –COOH, -OH, and –NH₂. As amended, Applicants' acrylic polymer lacks functional groups containing reactive hydrogen moieties.

In order for a reference to anticipate, the reference must disclose all the elements of the claim within the four corners of the document, and must also disclose those elements arranged as in the claim. EP'938 does not disclose all Applicants' claimed elements within the four corners of the document and in the combination claimed by Applicants and, as such, fails to anticipate the claimed invention. EP'938 discloses a pressure sensitive adhesive formed using an acrylic ester-based polymer and a liquid component and then crosslinking the polymer to allow it to gel.

Reconsideration and withdrawal of the Section 102 rejections of claims 1, 3-6, 9-14 and 22 are therefore respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 1, 3-7, 9-14 and 22 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over EP'938 in view of Weaver. The Examiner urges that it would have been obvious to the skilled artisan to replace the acrylamide monomer of EP '938 with octyl acrylamide disclosed in Weaver. The Examiner notes that one would have been motivated because Weaver teaches that the combination of alkyl (methyl)acrylate and octyl acrylamide has good tack and creates a polymer combination that is synergistic in nature, and one would have reasonably expected that formulating a polymer adhesive composition obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and octyl acrylamide to provide a polymer that has good tack and a synergistic adhesive nature (Office Action dated March 31, 2010, page 10, paragraph 4).

Applicants disagree.

To establish a *prima facie* case of obviousness, there must be some reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Moreover, the cited reference must teach or suggest all the claim limitations, and a reasonable expectation of success must be found elsewhere than in Applicants' disclosure. That is, the claim recitations must be found in the cited reference, the nature of the problem to be solved, or in the knowledge/understanding of the person of ordinary skill in the art. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, EP'938 in view of Weaver do not support a *prima facie* case of obviousness.

As an initial matter, Applicants wish to correct Examiner's reference to the teaching of Weaver teaching a combination of only 2-ethylhexyl acrylate and octyl acrylamide (Office Action dated March 31, 2010, page 10, third paragraph). It is not a mere combination of only 2-ethylhexyl acrylate and octyl acrylamide, but Weaver teaches that "...a specific combination of two particular acrylamide material[s] with 2-ethylhexyl acrylate creates a combination that is synergistic in nature..." (Weaver, col. 1, lines 51-53). Hence, Weaver teaches that a combination of two acrylamides (N-octyl acrylamide and methacrylamide) with 2-ethylhexyl acrylate results in the synergy.

There is no teaching, suggestion or motivation to combine the teachings of EP'938 and Weaver. EP'938 is directed to a reactive pressure sensitive adhesive formed using an acrylic ester-based polymer and a liquid component and then crosslinking the polymer to allow it to gel. The resultant pressure sensitive adhesive has a good balance of adhesion to the skin and skin-

unstimulating properties (EP'938, page 2, lines 54-56). This balance is achieved by preparing the adhesive using an acrylic ester-based polymer and crosslinking the polymer remedies the decreased cohesive force due to the incorporation of the liquid ingredients, and also to enable the pressure sensitive adhesive to show soft adhesion to the skin and to ease or disperse a stress to be imposed on the skin when the adhesive layer is stripped from the skin (*Id.*, page 2, line 55 to page 3, line 3). Hence, crosslinking the polymer is essential to achieve this soft adhesion to the skin. In order to crosslink the acrylic ester-based polymer, EP'938 teaches an alkyl (meth)acrylate and at least one reactive group such as, carboxyl group-containing monomers and hydroxyl group-containing monomers, are added to control of the amount of crosslinking sites or control tackiness properties (*Id.*, page 4, lines 33-37). Hence, EP'938 teaches that the use of reactive monomer components are required to crosslink the polymer, and thereby remedies the decreased cohesive force.

Weaver is directed to a pressure sensitive adhesive for sealing sponge rubber backed carpeting to floor surfaces (Weaver, col. 1, lines 19-30). This pressure sensitive adhesive has high peel strength, good tack and ability to reseal (*Id.*). Weaver teaches that an adhesive with the specific combination of 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide, creates a blend that is synergistic in nature (*Id.*, col. 1, lines 52-68). The presence of these three specific monomers result in an excellent pressure sensitive adhesive with tack (adhesive strength) greater than 800g/cm², and that the use of other acrylamide fails to give such adhesive strength (*Id.*, col. 1, line 64 to col. 2, line 3). Moreover, Weaver teaches that N-octyl acrylamide at a level greater than 7.5 parts per 100 parts of monomer, in conjunction with higher amounts of methacrylamide, surprisingly results in significantly higher levels of tack (*Id.*, col. 3, lines 61-69, and Table 2).

There is no reason or motivation to combine EP'938 and Weaver to arrive at the claimed invention in the absence of Applicants' own disclosure. The instant invention is directed to a non-reactive pressure sensitive adhesive composition comprising an acrylic polymer and a therapeutic agent, wherein the acrylic polymer (i) is prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers, polymerizable non-cyclic nitrogen-containing monomers and mixtures thereof; (ii) lacks functional groups containing reactive hydrogen moieties and (iii) contains no post-polymerization chemical crosslinking. The alkyl acrylate monomers and alkyl methacrylate monomers have up to about 18 carbon atoms in the alkyl group, and the polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, and mixtures thereof, and wherein said alkyl acrylate monomers and/or alkyl methacrylate monomers are present in the acrylic polymer in amounts of from about 50 to about 98%, based on a dry weight basis of the total monomer weight of the acrylic polymer, and said polymerizable non-cyclic nitrogen-containing monomers are present in the acrylic polymer in amounts from about 2 to about 50%, based on a dry weight basis of the total monomer weight of the acrylic polymer. Hence, the instant invention is directed to a non-reactive pressure sensitive adhesive that lacks reactive components that can further crosslink.

One skilled in the art would not be led to combine the teachings of a pressure sensitive adhesive which requires crosslinking to form a gel with the specific three-component combination taught in Weaver as having synergistic effect. EP'938 is directed to a reactive pressure sensitive adhesive which requires the use of a reactive monomer, carboxyl group-

containing monomers and hydroxyl group-containing monomers, to crosslink the polymer to form a gel, which can be used on skin. Weaver is directed to a pressure sensitive adhesive with the specific combinations of 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide, which has high tack and can be used for sealing sponge rubber backed carpeting to floor surfaces. As such, there is no reason or motivation to combine EP'938 and Weaver to arrive at the claimed invention in the absence of Applicants' own disclosure. The combined references fail to teach or suggest a non-reactive pressure sensitive adhesive that does not require post-polymerization chemical crosslinking.

There is no predictability that the combination of EP'938 and Weaver would result in the instant adhesive. Because of the required carboxyl group and hydroxyl-group containing monomers in EP'938, the combined teachings would result in crosslinked gel with 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide. However, it is not predictable that three-component carpeting adhesive of Weaver, which is taught to be synergistic in nature, can be used on skin without further crosslinking.

Even if requisite motivation is determined to combine the teaching of EP'938 and Weaver (a proposition which Applicants dispute), the purported combination would not lead to the instant invention. The purported combination may be unable to remedy the decreased cohesive force, and thereby increase skin stimulation, which is not desired for skin application. Moreover, the addition of carboxyl group and hydroxyl-group containing monomers may also destroy the synergistic effect of the 3-component carpet adhesive, and may result in lower tack.

Furthermore, EP'938 and Weaver teach away from combining the two references together. EP'938 teaches that the use of a reactive monomer, carboxyl group-containing

monomers and hydroxyl-containing monomers are essential components to form the acrylic ester-based polymers which is applied to the skin (EP'938, page 4, lines 3-37). In contrast, the instant invention is directed to utilizing non-reactive pressure sensitive adhesive, which lack functional groups containing reactive hydrogen moieties such as -COOH, -OH, and -NH₂. As such, a skilled artisan would not look to EP'938 to develop a non-reactive pressure sensitive adhesive which does not require any post-polymerization chemical crosslinking. Moreover, Weaver teaches that the specific combination of 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide has a synergistic effect on tack (Weaver, col. 1, lines 53-56). As such, by introducing a new component and/or removing a component, one cannot realize this synergy.

As such, the invention of claims 1, 3-7, 9-14 and 22 would not have been obvious to one of ordinary skill in the art from the disclosures of EP'938 in view of Weaver. Withdrawal is requested.

Claims 15-17 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over EP'938 in view of Weaver and further in view of Chono et al. (U.S. Patent 6,139,866, hereinafter, "Chono"). The Examiner urges that while EP'938 teaches delivery use of analgesics, sedatives and hypnotic drugs, the use of fentanyl is not explicitly taught (Office Action dated March 31, 2010, page 12, paragraph 6). It is, however, the position of the Examiner that it would have been obvious to the skilled artisan to replace the analgesic, sedative or hypnotic drugs of EP '938 with fentanyl that is taught in Chono as being suitable for transdermal administration (*Id.*, page 13, paragraph 1).

Applicants disagree.

The arguments set forth above related to EP'938 and Weaver are equally applicable here.

Chono, as a tertiary reference, fails to cure the defect of EP'938 and Weaver so as to render obvious the claimed invention. Chono teaches that the solubility of fentanyl citrate in non-aqueous base is low, and thus, addition of sodium acetate to the pressure sensitive adhesive provides higher transdermal permeation rates of fentanyl.

While Chono teaches a rubber based pressure sensitive adhesive which includes polyisobutylene (PIB), styrene-isoprene-styrene block copolymer (SIS), (see Chono, col. 2, lines 57-61), Chono fails to teach or suggest utilizing an acrylic polymer prepared from alkyl acrylate monomers, alkyl methacrylate monomers, polymerizable non-cyclic nitrogen-containing monomers and mixtures. Again, the instant invention is directed to a non-reactive pressure sensitive adhesive, where the adhesive composition lacks functional groups such as -COOH, -OH, -NH₂. As such, a skilled artisan would not look to combine the teachings of EP'938, Weaver, and Chono, where sodium acetate is purposefully added, to arrive at the instant invention.

Moreover, the combined disclosures of EP'938, Weaver and Chono would not have led to an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking. Use of fentanyl in as a therapeutic agent to be delivered would not have resulted in an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking.

Claims 15-17 are not obvious over EP'938 in view of Weaver, and further in view of Chono et al. Reconsideration and withdrawal of this Section 103 rejection is requested.

Claims 18, 19, 21 and 23 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over EP'938 in view of Weaver and further in view of Muller et al. (US 5,458,885, hereinafter "Muller"). EP'938 is cited by the Examiner as teaching the use of two or more alkyl (meth)acrylates in the polymer. Weaver is cited as teaching octyl acrylamide. While the Examiner acknowledges that 2-ethylhexyl acrylate and methyl acrylate, as required by claims 18, 19, 21 and 23, are not explicitly taught in the combined disclosures of EP'938 and Weaver, the Examiner applies Muller to cure this defect. Muller is cited by the Examiner as teaching transdermal systems comprising polymer made of methyl acrylate and 2-ethylhexyl acrylate. It is the Examiner's position that it would have been obvious to the skilled artisan to replace the acrylate monomers of EP'938 and Weaver with methyl acrylate and 2-ethylhexyl acrylate disclosed in is taught in Muller et al.

Applicants disagree.

The arguments set forth above related to EP'938 and Weaver are equally applicable here. Muller, as a tertiary reference, fails to cure the defect of so EP'938 and Weaver as to render obvious the claimed invention. Muller is directed to employing a basic active component in a pressure sensitive adhesive polymer material, which also has basic characteristics through polymerization (Muller, Abstract and col. 18-21, lines). Because of the drug and adhesive interactions, the instant invention is directed to a non-reactive pressure sensitive adhesive so that this technology can be extended and used as a delivery option for broader ranges of drugs (Specification, page 3, lines 8-10). Again, the instant invention is directed to a non-reactive pressure sensitive adhesive, where the adhesive composition lacks functional groups such as -COOH, -OH, -NH₂. As such, a skilled artisan would not look to combine the teachings of

EP'938, Weaver and Muller to develop a non-reactive pressure sensitive adhesive.

In addition, the combined disclosures of EP'938, Weaver and Muller would not have led to an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking. There is no suggestion that would motivate the skilled artisan to use only those monomers that would result in an acrylate polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking, as such an adhesive would be contrary to the teachings of EP'938. There is no disclosure that would motivate the skilled artisan not use the methacrylamide monomer of Weaver, as such an absence of a required component would be contrary to the teachings of Weaver. The further combination of Muller with the combined disclosures of EP'938 in view of Weaver would not have led the skilled artisan to Applicants' claimed adhesive.

Claims 18, 19, 21 and 23 are not obvious over EP'938 in view of Weaver and further in view of Muller et al. Reconsideration and withdrawal of this Section 103 rejection is requested.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action. Accordingly, an early and favorable reconsideration of the rejections and an allowance of all of pending claims are earnestly solicited.

Respectfully submitted,

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